

National Cancer Institute
Institutional Review Board

AGENDA
March 9, 2015
1:00 – 5:00 pm
10 CRC/3-1608

1. **Review of Draft Minutes, February 23, 2015**
2. **Announcements**
3. **Old Business**
4. **New Business**
5. **Problem Report Forms**
6. **Other Expedited Actions**
7. **Continuing Reviews**
8. **Response to Stips** 11C0160I, "A Pilot/ Phase II Study of Pentostatin Plus Cyclophosphamide Immune Depletion to Decrease Immunogenicity of SS1P in Patients with Mesothelioma, Lung Cancer or Pancreatic Cancer" - Raffit Hassan, PI
9. **Response to Stips** 10C0166E, "Collection of Human Samples to Study Hairy Cell and Other Leukemias and to Develop Recombinant Immunotoxins for Cancer Treatment" - Robert Kreitman, PI
10. **Amendment** 11C0016-K, "Rapamycin-Resistant T-Cell Therapy of Multiple Myeloma: Relapse Prevention and Relapse Therapy" - Daniel Fowler, PI
11. **Amendment** 09C0111K, "A Phase I, Dose-Escalation Study of the Safety, Tolerability, and Pharmacokinetics of Intravenous Dimethane Sulfonate (DMS612, NSC 281612) in Advanced Malignancies"—Susan Bates, PI
12. **Initial Review** P152179, "Expanded Access (Compassionate Use) Treatment Protocol with Rindopepimut (CDX-110)" - Mark Gilbert, PI
13. **Initial Review** P131446, "Neoadjuvant Androgen Deprivation and Enzalutamide: Using Multiparametric MRI to Evaluate Intraprostatic Tumor Responses and Androgen Resistance Patterns in Newly Diagnosed Prostate Cancer" - William Dahut, PI
14. **Initial Review** P142114, "A Randomized, Double-Blind, Phase 2 Trial of GI-6301 (Yeast-Brachyury Vaccine) Versus Placebo in Combination with Standard of Care Definitive Radiotherapy in Locally Advanced, Unresectable, Chordoma" - Christopher Heery, PI
15. **Initial Review** P141726, "Phase I/II Study of the Anti-programmed Death Ligand-1 Antibody (a PD-L1 inhibitor) MEDI4736 in Combination with Olaparib or Cediranib for Advanced Solid Tumors and Recurrent Ovarian Cancer" - Jung-Min Lee, PI